

## **REMARKS**

The title of the invention has been amended to remove the term “prophylaxis”.

Claims 4, 8 and 9 have been amended and new claim 10 has been added.

Claim 4 has been amended to add two additional species of 1,2,5-benzothiadiazepines.

Support for these species may be found in the specification of the corresponding published PCT application (WO 04/089350) at, *inter alia*, page 16, lines 15-21.

Claims 8 and 9 have been amended to include the species recited in new method of treatment claim 10.

New claim 10 recites a method of treating functional constipation or C-IBS via administration of the recited 1,5-benzothiazepines. Support for these species may be found in the specification of the corresponding published PCT application (WO 04/089350) at, *inter alia*, page 6, line 14 to page 9, line 14.

Applicants submit that no prohibited new matter has been introduced by the amendments to claims 4, 8 and 9, or by the new claim 10.

Further, Applicants submit that the addition of two specific compounds to claim 4 and several specific compounds to new claim 10 does not prompt a new search since the added compounds are IBAT inhibitors and the Examiner has already cited Lindqvist as allegedly encompassing IBAT inhibitors not limited by chemical structure. Accordingly, Applicants respectfully request entry of the new claim and proposed claim amendments into the record.

### **1. Objection to the Title**

The Examiner objects to the inclusion of the term “prophylaxis” in the title.

Without acquiescing to the merits of the Examiner’s objection, and in an effort to expedite allowance of the claims, Applicants have amended the title to remove the contested term.

**2. Objection to the Claims**

The Examiner objects to claim 4 as containing an incorrect spelling of the term “hydrolyzable”.

Applicants submit that “hydrolysable” as currently recited in claim 4 is the British English spelling of this term and is correct as is. Applicants point to MPEP 608.01 in which it is stated that

“Examiners should not object to the specification and/or claims in patent applications merely because applicants are using British English spellings (e.g., colour) rather than American English spellings. It is not necessary to replace the British English spellings with the equivalent American English spellings in the U.S. patent applications.”

Accordingly, Applicants respectfully request that this objection be withdrawn.

**3. Rejection under 35 U.S.C. 103(a)**

Claims 4, 8 and 9 are rejected as allegedly obvious over U.S. 2005/0124557 to Lindqvist (“Lindqvist”) in view of U.S. Patent 7,132,416 to Starke *et al.* (“Starke”). According to the Examiner, Lindqvist suggests that pharmaceutical compositions comprising IBAT inhibitors may be employed for a laxative effect. The Examiner acknowledges that Lindqvist fails to recite the specific compounds that are recited in Applicants’ claims but relies on Starke for describing these compounds. The Examiner asserts that one skilled in the gastroenterology art would have been motivated to employ an IBAT inhibitor to treat functional constipation or constipation-predominant irritable bowel syndrome.

Applicants submit that under 35 U.S.C. 103(c), Lindqvist should be disqualified as prior art available for assertion against Applicants’ claims. In satisfying the first requirement of 103(c), Lindqvist would only qualify as prior art to the subject application under 102(e), (f) or (g) given that Lindqvist was filed on January 23, 2003 (international filing date) compared to the April 5, 2003 effective filing date (based on GB 0307918.3) of the subject application. In satisfying the second requirement of 103(c), both Lindqvist and the subject application were, at the time of filing of the subject application, owned by the same entity or subject to an obligation

of assignment to the same entity (*i.e.*, AstraZeneca AB). Accordingly, Applicants believe that Lindqvist should be disqualified as prior art under 103(c). Applicants submit that Starke by itself does not render Applicants' claims obvious at least for the reason that Starke does not teach or suggest the subject matter in Lindqvist relied upon by the Examiner in asserting a rejection under 103(a). Therefore, Applicants respectfully request that this rejection be withdrawn.


**4. Conclusion**

All grounds for objection and or rejection having been fully addressed by the above amendments and remarks, and it is believed that each of claims 4, 8, 9 and 10 is now in condition for allowance. However, if there are any questions or remaining issues that need to be resolved before allowance, it is suggested that the Examiner telephone the undersigned to see if their resolution can be expedited.

**Except** for issues payable under 37 C.F.R. 1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. 1.16 and 1.17 which may be required, including any required extension of time fees, or to credit any overpayment to Deposit Account 50-0310. This paragraph is intended to be a **constructive petition for extension of time** in accordance with 37 C.F.R. 1.136(a)(3).

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Respectfully submitted,  
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